APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jaime L. Rugnetta et al.	Examiner: Nicole R. Kramer
Serial No.: 10/670,985	Group Art Unit: 3762
Filed: September 25, 2003	Docket: 279.607US1

For: LEAD SYSTEM HAVING LEAD BODY WITH MINIMIZED CROSS-SECTION

APPEAL BRIEF UNDER 37 CFR § 41.37

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on November 13, 2006, from the Final Rejection of claims 1-20 of the above-identified application, as set forth in the Final Office Action dated on June 13, 2006.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $500.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellant respectfully requests consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, CARDIAC PACEMAKERS, INC.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on September 25, 2003 with claims 1-20. A non-final Office Action was mailed January 27, 2006, and a response was filed May 26, 2006. A Final Office Action (hereinafter "the Final Office Action") was mailed June 13, 2006. Claims 1-20 stand finally rejected, remain pending, and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

An Amendment and Response to the Final Office Action was filed on October 13, 2006, presenting an amendment to claim 8 and new claims 21-25. Neither the amendment to claim 8 nor new claims 21-25 were entered. However, the Advisory Action of October 27, 2006, stated "the amendments to claim 8 would be entered after-final if a separate paper were filed containing only such amendments. . . . Such amendments are believed to overcome the 112 rejection set forth in the Final Office Action of 6/13/06, and thus place the application in better condition for appeal." As recommended by Supervisor Angela Sykes during a telephone conversation on January 3, 2007, a Supplemental Amendment including only the previously-submitted amendment to claim 8 was submitted on January 3, 2007. Entry of the amendment was subsequently confirmed during a telephone conversation with Supervisor Sykes on January 9, 2007. As such, an amendment to claim 8 has been made after the Final Office Action of June 13, 2006. The claims listed in the Claims Appendix reflect claims 1-20 as they currently exist.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 relates to a lead assembly (*see, e.g.*, Application at FIGS. 1-3 at 100) including a lead body (*see, e.g.*, Application at FIGS. 1-6 at 110) extending from a lead proximal end (*see, e.g.*, Application at FIG. 1 at 112) to a lead distal end (*see, e.g.*, Application at FIGS. 1 and 2A at 114) and having an intermediate portion (*see, e.g.*, Application at FIGS. 1, 2A, and 3 at 118) therebetween. The lead body includes a tine interface section (*see, e.g.*, Application at FIG. 2A at 122). At least one tine (*see, e.g.*, Application at FIGS. 2A, 3, 4, and 6 at 150) is coupled with the lead body at a tine coupling portion (*see, e.g.*, Application at FIG. 2A at 152). Each at least one tine has a top surface (*see, e.g.*, Application at FIG. 2A at 160) and a bottom surface (*see, e.g.*, Application at FIGS. 2A, 3, and 6 at 162). The at least one tine has a first position (*see, e.g.*, Application at page 5, paragraph [0012], and FIGS. 2A and 3) extended away from the lead body and a second collapsed position (*see, e.g.*, Application at page 5, paragraph [0012], and FIG. 6). At least one first recessed portion (*see, e.g.*, Application at FIGS. 3 and 4 at 182) is formed on the lead body at a first longitudinal location along the tine interface section of the lead body. At least one second recessed portion (*see, e.g.*, Application at FIG. 3 at 190) is formed on the lead body at a second longitudinal location along the tine interface section of the lead body. The at least one first recessed portion is longitudinally disposed between the tine coupling portion and the at least one second recessed portion (*see, e.g.*, Application at FIG. 3). The at least one first recessed portion is recessed away from the bottom surface of the at least one tine when the at least one tine is disposed in the second collapsed position (*see, e.g.*, Application at page 7, paragraph [0017], and FIG. 6).

Independent claim 8 relates to a lead assembly (*see, e.g.*, Application at FIGS. 1-3 at 100) including a lead body (*see, e.g.*, Application at FIGS. 1-6 at 110) extends from a lead proximal end (*see, e.g.*, Application at FIG. 1 at 112) to a lead distal end (*see, e.g.*, Application at FIGS. 1 and 2A at 114) and having an intermediate portion (*see, e.g.*, Application at FIGS. 1, 2A, and 3 at 118) therebetween. The lead body has a tine interface section (*see, e.g.*, Application at FIG. 2A at 122). At least one tine (*see, e.g.*, Application at FIGS. 2A, 3, 4, and 6 at 150) is coupled with the lead body at a tine coupling portion (*see, e.g.*, Application at FIG. 2A at 152). Each at least one tine has a top surface (*see, e.g.*, Application at FIG. 2A at 160) and a bottom surface

(*see, e.g.*, Application at FIGS. 2A, 3, and 6 at 162). The at least one tine has a first position (*see, e.g.*, Application at page 5, paragraph [0012], and FIGS. 2A and 3) extended away from the lead body and a second collapsed position (*see, e.g.*, Application at page 5, paragraph [0012], and FIG. 6). At least one first portion (*see, e.g.*, Application at FIGS. 3 and 4 at 182) is formed on the lead body at a first location along the tine interface section of the lead body. The at least one first portion has a first cross-sectional shape (*see, e.g.*, Application at page 6, paragraph [0016], and FIG. 4). At least one second portion (*see, e.g.*, Application at FIG. 3 at 190) is formed on the lead body at a second location along the tine interface section of the lead body. The at least one second portion has a second cross-sectional shape (*see, e.g.*, Application at page 6, paragraph [0016], and FIG. 5). The first cross-sectional shape is different than the second cross-sectional shape (*see, e.g.*, Application at page 6, paragraph [0016], and FIGS. 4 and 5). The at least one first portion is longitudinally disposed between the tine coupling portion and the at least one second portion (*see, e.g.*, Application at FIG. 3).

Independent claim 15 relates to a method (*see, e.g.*, Application at page 8, paragraphs [0020] and [0021]) including disposing a conductor (*see, e.g.*, Application at FIG. 2A at 116) within a lead body (*see, e.g.*, Application at FIGS. 1-6 at 110). The lead body includes a tine interface portion (*see, e.g.*, Application at FIG. 2A at 122). One or more tines (*see, e.g.*, Application at FIGS. 2A, 3, 4, and 6 at 150) are coupled with the lead body. The one or more tines are collapsible from a first extended position (*see, e.g.*, Application at page 5, paragraph [0012], and FIGS. 2A and 3) to a second collapsed position (*see, e.g.*, Application at page 5, paragraph [0012], and FIG. 6). The one or more tines have a top surface (*see, e.g.*, Application at FIG. 2A at 160) and a bottom surface (*see, e.g.*, Application at FIGS. 2A, 3, and 6 at 162). A first recessed portion (*see, e.g.*, Application at FIGS. 3 and 4 at 182) is formed along the lead body at a first longitudinal location along the tine interface portion, wherein forming the first recessed portion includes recessing the first recessed portion away from the bottom surface when the one or more tines are disposed in the second collapsed position (*see, e.g.*, Application at page 7, paragraph [0017], and FIG. 6). A second recessed portion (*see, e.g.*, Application at FIG. 3 at 190) is formed along the lead body at a second longitudinal location along the tine interface portion.

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and its legal equivalents for a complete statement of the invention.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1) Was a *prima facie* case of anticipation under 35 U.S.C. § 102(b) properly made with respect to claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 using Huepenbecker et al. (U.S. Patent No. 6,289,251)?

2) Was a *prima facie* case of anticipation under 35 U.S.C. § 102(b) properly made with respect to claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 using Laske et al. (U.S. Patent No. 5,807,399)?

3) Was a *prima facie* case of obviousness under 35 U.S.C. § 103(a) properly made with respect to claims 2, 5, 11, 13, 17, and 18 using Huepenbecker et al. in view of Alferness et al. (U.S. Patent No. 5,531,781)?

4) Was a *prima facie* case of obviousness under 35 U.S.C. § 103(a) properly made with respect to claims 2, 5, 11, and 17 using Laske et al.?

5) Was a *prima facie* case of obviousness under 35 U.S.C. § 103(a) properly made with respect to claims 13 and 18 using Laske et al. in view of Alferness et al.?

7. ARGUMENT

A) The Applicable Law

A.1) The Applicable Law under 35 U.S.C. §102(b)

In order for a prior art reference to anticipate under 35 U.S.C. § 102, "every element of the claimed invention must be identically shown in a single reference." (emphasis added). *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In addition, in order to anticipate the elements in the single reference "must be arranged as in the claim under review." *Id.*, (quoting *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1948)). Also, "the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1989). Additionally, "[i]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Hockerson-Halberstadt v. Avia Group International, Inc.*, 222 F.3d 951, 956 (citing *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977).

A.2) The Applicable Law under 35 U.S.C. §103(a)

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d (BNA) 1596, 1598 (Fed. Cir. 1988). In combining prior art references to construct a *prima facie* case, the Examiner must show some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant teaching of the references. *Id.* In agreement with the *In re Fine* court, the M.P.E.P. provides explicit direction to the Examiner:

> In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally,

> the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *M.P.E.P.* § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 1991)).

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d (BNA) 1443 (Fed. Cir. 1992). However, while it is not necessary that the cited references or prior art specifically suggest making the combination, there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses. One of ordinary skill in the art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 U.S.P.Q.2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 U.S.P.Q. 171, 174 (C.C.P.A. 1979)). However, the level of skill is not that of the person who is an innovator but rather that of the person who follows the conventional wisdom in the art. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 474, 227 U.S.P.Q. 293, 298 (Fed. Cir. 1985). The requirement of a suggestion or motivation to combine references in a *prima facie* case of obviousness is emphasized in the Federal Circuit opinion, *In re Sang Su Lee*, 277 F.3d 1338; 61 U.S.P.Q.2D 1430 (Fed. Cir. 2002), which notes that the motivation must be supported by evidence in the record.

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). References must be considered in their entirety, including parts that teach away from the claims. *See* MPEP § 2141.02. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963). The fact that references can be combined or modified does not render the

resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); M.P.E.P. § 2143.01.

B. Discussion of the Rejections

B.1) Rejection of Claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 Under 35 U.S.C. § 102(b) for Anticipation by Huepenbecker et al.

Claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 were rejected under 35 U.S.C. § 102(b) for anticipation by Huepenbecker et al. (U.S. Patent No. 6,289,251). Appellant respectfully traverses this rejection.

Appellant cannot find all of the elements of the claims in Huepenbecker et al. For instance, Appellant cannot find in Huepenbecker et al. a recessed portion recessed away from the bottom surface of the tine when the tine is disposed in the second collapsed position, as recited in claims 1 and 14, or forming a first recessed portion along the lead body along the tine interface portion including recessing the first recessed portion away from the bottom surface when the one or more tines are disposed in the second collapsed position, as recited in claim 15. Appellant further cannot find in the reference the first portion along the tine interface second having a first cross-sectional shape that is different than a second cross-sectional shape, as recited in claim 8. Claims 3, 4, 6, and 7 also include the recitations of claim 1, claims 9, 10, and 14 include the recitations of claim 8, and claims 16, 19, and 20 include the limitations of claim 15. For at least this reason, claims 3, 4, 6, 7, 9, 10, 14, 16, 19, and 20 are likewise not anticipated by Huepenbecker et al.

Appellant notes that Huepenbecker et al. does not include any figures illustrating tines in a collapsed position. According to the Final Office Action at page 3, "when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine." In the Response to Arguments section at page 12, the Final Office Action further states that "the bottom surface of tines would contact the outer surface of sleeve 36 (which forms the second recessed portion), thus leaving the first portion (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine." This statement is reiterated on page 3 of the Advisory Action, dated October 27, 2006 (hereinafter "the Advisory Action"). While the Advisory Action at page 3 purports to

cite references related to "passive tines . . . that . . . fold/collapse against the lead body during insertion into the patient", Appellant cannot find in Huepenbecker et al. or any of the cited references discussion related to the tines being recessed away from a first recessed portion. Appellant respectfully submits that Huepenbecker et al. does not enable such statements, and therefore the Examiner is relying on either Official Notice, or the personal knowledge of the Examiner. Appellant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Appellant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection.

With respect to claims 3, 9, 19, and 20, the Final Office Action states at page 4, "the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion." The Advisory Action at page 4 goes on to contend that "the axial view of Figure 4 shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion". While it is unclear on what the Final Office Action and the Advisory Action rely to make such statements, Appellant cannot find support in the specification for such assertions. Appellant wonders how the Final Office Action and the Advisory Action can draw such conclusions having only one cross section of the lead taken along an axial plane in Fig. 4 of Huepenbecker et al. Appellant asserts that one skilled in the art could not determine the cross-sectional areas of what the Final Office Action identifies as the first and second recessed portions of Huepenbecker et al. given only a cross section along a single axial plane, nor would one skilled in the art be able to identify the widths of what the Final Office Action identifies as the first and second recessed portions of Huepenbecker et al. as being diameters. Appellant submits that Huepenbecker et al. does not anticipate claims 3, 9, 19, and 20, and is not an enabling reference. Reconsideration and allowance of claims 3, 9, 19, and 20 are respectfully requested.

Appellant notes that Huepenbecker et al. does not state the drawings are to scale. The Final Office Action states on page 4, "it appears from Figure 4 that the cross-sectional area at the lead distal end . . . is approximately the same as the cross-sectional area of the tine coupling portion. Accordingly, the cross-sectional area of the tine coupling area is necessarily 'less than 10% smaller' than the cross-sectional area of the lead distal end." The Final Office Action states on page 13 that "the claims as written do not require any precise proportions or sizes of the first

and second recessed portions." The Advisory Action at page 4 goes on to contend "that Figure 4 illustrates that the cross-sectional area at the lead distal end . . . is approximately the same as the cross-sectional area of the tine coupling portion. As such, the cross-sectional area of the tine coupling area is approximately equal to the cross-sectional area of the lead distal end, and thus necessarily 'less than 10% smaller' than the cross-sectional area of the lead distal end." However, because the drawings of Huepenbecker et al. do not define precise proportions and the specification is completely silent with respect to the issue, Appellant respectfully asserts that the drawings of Huepenbecker et al. cannot be used to anticipate claim 4, which recites "the first cross-sectional area is less than 10% smaller than the second cross-sectional area". That is, Appellant submits that because the patent drawings of Huepenbecker et al. do not define the precise proportions of the elements and because Appellant cannot find discussion in the specification regarding the issue, the figures of Huepenbecker et al. may not be relied on to show particular sizes to anticipate claim 4. Accordingly, Appellant asserts that the rejection is improper, and reconsideration and allowance of claim 4 are respectfully requested.

With respect to claim 7, the Final Office Action states at pages 4-5 that "[a]s shown in Fig. 4, the diameters of the spacer 34, the first recessed portion, and the second recessed portion are each different from one another." With respect to claim 8, the Final Office Action states at page 5, "the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion." In the Response to Arguments section at page 13, the Final Office Action essentially reiterates this statement, further stating that "Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape." Appellant cannot find support in the specification for these assertions. Appellant can find no recitations related to the cross-sectional areas of any portions of the Huepenbecker et al. device. Further, it is unclear how these conclusions can be reached when Figure 4 only illustrates a longitudinal cross-section. Accordingly, reconsideration and allowance of claims 7 and 8 are respectfully requested.

For at least these reasons, Appellant respectfully asserts that claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 are not anticipated by Huepenbecker et al. and requests reconsideration and withdrawal of this rejection.

B.2) Rejection of Claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 Under 35 U.S.C. § 102(b) for Anticipation by Laske et al.

Claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 were rejected under 35 U.S.C. § 102(b) for anticipation by Laske et al. (U.S. Patent No. 5,807,399). Appellant respectfully traverses this rejection.

Appellant cannot find all of the elements of the claims in Laske et al. For instance, Appellant cannot find in Laske et al. a recessed portion recessed away from the bottom surface of the tine when the tine is disposed in the second collapsed position, as recited in claim 1 and 14, or forming a first recessed portion along the lead body along the tine interface portion including recessing the first recessed portion away from the bottom surface when the one or more tines are disposed in the second collapsed position, as recited in claim 15. Appellant further cannot find in the reference the first portion along the tine interface second having a first cross-sectional shape that is different that a second cross-sectional shape as recited in claim 8. Claims 3, 4, 6, and 7 also include the limitations of claim 1, claims 9, 10, and 14 include the limitations of claim 8, and claims 16, 19, and 20 include the limitations of claim 15 and are likewise not anticipated by Laske et al. For at least this reason, claims 3, 4, 6, 7, 9, 10, 14, 16, 19, and 20 are likewise not anticipated by Laske et al.

Appellant notes that Laske et al. does not include any figures illustrating tines in a collapsed position. According to the Final Office Action at page 6, "when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine." In the Response to Arguments section at pages 14-15, the Final Office Action further states that "the bottom surface of tines would contact the outer surface lead body (which forms the second recessed portion), thus leaving the first portion or groove 152 (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine." This statement is reiterated on page 6 of the Advisory Action. While the Advisory Action at page 5 purports to cite references related to tines "formed of a flexible material such that the tines fold/collapse against the lead body during insertion into the patient", Appellant cannot find in Laske et al. or any of the cited references discussion related to the tines being recessed away from a first recessed portion. Appellant respectfully submits that Laske et al. does not enable such statements, and therefore the Examiner is relying on either

Official Notice, or the personal knowledge of the Examiner. Appellant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Appellant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection.

With respect to claims 3, 9, 19, and 20, the Final Office Action states at page 6, "the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion." The Advisory Action at page 6 goes on to contend that "the axial view of Figure 5 shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion". While it is unclear on what the Final Office Action and the Advisory Action rely to make such statements, Appellant cannot find support in the specification for such assertions. Appellant wonders how the Final Office Action and the Advisory Action can draw such conclusions having only one cross section of the lead taken along an axial plane in the figures of Laske et al., and, in particular, Fig. 5 referenced by the Final Office Action and the Advisory Action. Appellant asserts that one skilled in the art could not determine the cross-sectional areas of what the Final Office Action identifies as the first and second recessed portions of Laske et al. given only a cross section along a single axial plane, nor would one skilled in the art be able to identify the widths of what the Final Office Action identifies as the first and second recessed portions of Laske et al. as being diameters. Appellant submits that Laske et al. does not anticipate claims 3, 9, 19, and 20, and is not an enabling reference. Reconsideration and allowance of claims 3, 9, 19, and 20 are respectfully requested.

Appellant notes that Laske et al. does not state the drawings are to scale. With respect to claim 4, the Final Office Action states on page 6, "it appears from Figure 5 that the cross-sectional area at the lead distal end is slightly larger than the cross-sectional area of the tine coupling portion. Examiner considers the cross-sectional area of the tine coupling area to be approximately 'less than 10% smaller' than the cross-sectional area of the lead distal end." Initially, Appellant asserts that the Examiner is using personal knowledge, and Appellant requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Additionally, as stated above, the specification of Laske et al. fails to state the drawings are to scale. The Final Office Action states on page 15 that "the claims as written do not require any precise proportions or sizes of the first and second recessed portions." However, because the drawings of Laske et

al. do not define precise proportions and the specification is completely silent with respect to the issue, Appellant respectfully asserts that the drawings of Laske et al. cannot be used to anticipate claim 4, which recites "the first cross-sectional area is less than 10% smaller than the second cross-sectional area". That is, Appellant submits that because the patent drawings of Laske et al. do not define the precise proportions of the elements and because Appellant cannot find discussion in the specification regarding the issue, the figures of Laske et al. may not be relied on to show particular sizes to anticipate claim 4. Accordingly, Appellant asserts that the rejection is improper, and reconsideration and allowance of claim 4 are respectfully requested.

With respect to claim 7, the Final Office Action states at page 7 "the length of the first recessed portion is less than the tine length," and "[a]s shown in Fig. 5, the diameters of the sheath 122, the first recessed portion, and the second recessed portion are each different from one another." With respect to claim 8, the Final Office Action states at page 7, "the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion." In the Response to Arguments section at page 15, the Final Office Action essentially reiterates this statement, further stating that "Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape." Appellant cannot find support in the specification for these assertions. Appellant can find no disclosure related to the cross-sectional areas of any portions of the Laske et al. device. Further, it is unclear how these conclusions can be reached when the figures of Laske et al., in particular Fig. 5 as referenced by the Final Office Action, only illustrates a longitudinal cross-section. Accordingly, reconsideration and allowance of claims 7 and 8 are respectfully requested.

For at least these reasons, Appellant respectfully asserts that claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 are not anticipated by Laske et al. and requests reconsideration and withdrawal of this rejection.

B.3) Rejection of Claims 2, 5, 11, 13, 17, and 18 Under 35 U.S.C. § 103(a) as Being Unpatentable over Huepenbecker et al. in view of Alferness et al.

Claims 2, 5, 11, 13, 17, and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Huepenbecker et al. in view of Alferness et al. (U.S. Patent No. 5,531,781). Appellant respectfully traverses this rejection.

Appellant submits that the rejection has not established a case of obviousness since the rejection has not shown that each element is taught by the cited patents. Appellant incorporates the above-discussion with respect to the independent claims, and how Huepenbecker et al. fails to establish all of the elements. Alferness et al. does not supply the missing elements.

Notwithstanding that all of the elements cannot be found in the cited references, the Final Office Action fails to provide a legally sufficient motivation to combine the references. The Final Office Action states at page 8 "[i]t would have been obvious . . . in order to ensure that lead body is sufficiently strong during implantation." The Final Office Action further states on page 16 and the Advisory Action reiterates at pages 6-7 that "the motivation to combine the references . . . is based on common sense and in the knowledge generally available to one of ordinary skill in the art." The Final Office Action at page 16 and the Advisory Action at page 7 further contend that "[a]dded material in the area of recesses 167, as shown in Figure 10 of Alferness et al., would necessarily strengthen the lead body at the distal end thereof such that it is sufficiently strong to be tracked through a patient's vasculature system to the implantation site of the endocardium." Appellant respectfully submits that these statements are unsupported by the cited references. Appellant respectfully submits that neither Huepenbecker et al. nor Alferness et al. enables such statements, and therefore the Final Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Appellant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertions. Appellant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertions, or in the alternative, withdrawal of these assertions from the rejection. Furthermore, it is unclear why Huepenbecker et al. would be in need of such a selective modification. Reconsideration and allowance of claims 2, 5, 11, 13, 17, and 18 are respectfully requested.

B.4) Rejection of Claims 2, 5, 11, and 17 Under 35 U.S.C. § 103(a) as Being Unpatentable over Laske et al.

Claims 2, 5, 11, and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Laske et al. Appellant respectfully traverses this rejection. Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. *See* 37 C.F.R. § 1.75(c).

Appellant submits that the rejection has not established a case of obviousness since the rejection has not shown that each element is taught by the cited patents. Appellant incorporates the above-discussion with respect to the independent claims, and how Laske et al. fails to establish all of the elements. Appellant submits that Alferness et al. does not supply the missing elements.

Notwithstanding that all of the elements cannot be found in Laske et al. (or Alferness et al.), the Final Office Action fails to provide a legally sufficient motivation to combine the references. The Final Office Action states at pages 9-10 "[i]t would have been obvious . . . to modify the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body (so long as the sheath 122 may be readily separated when force is applied thereto) in order to ensure that sheath 122 is sufficiently strong during implantation." The Final Office Action further states on page 16 and the Advisory Action at pages 6-7 reiterates that "the motivation to combine the references . . . is based on common sense and in the knowledge generally available to one of ordinary skill in the art." The Final Office Action at page 16 and the Advisory Action at page 7 further contend that "[a]dded material in the area of recesses 167, as shown in Figure 10 of Alferness et al., would necessarily strengthen the lead body at the distal end thereof such that it is sufficiently strong to be tracked through a patient's vasculature system to the implantation site of the endocardium." Appellant respectfully submits that these statements are unsupported by the cited references. Appellant respectfully submits that Laske et al. (or Alferness et al.) does not enable such statements, and therefore the Final Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Appellant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertions. Appellant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertions, or in the alternative, withdrawal of these assertions from the rejection.

Furthermore, when considered as a whole, Laske et al. teaches away from making the selective modification as suggested in the Final Office Action. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the

prior art. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963). The purpose of element 152 of Laske et al. is to create a weakened portion. (*See* Laske et al., col. 7, lines 15-31.) To use hindsight reconstruction and say element 152 could be made to extend only partially around the perimeter to strengthen the lead is opposite of what the reference describes, and would frustrate the purpose of element 152, that is, to allow the lead to separate. Element 152 of Laske et al. is designed to allow for a weakened portion of the lead, which teaches away from trying to use the same element to make the lead stronger. Accordingly, reconsideration and allowance of claims 2, 5, 11, and 17 are respectfully requested.

B.5) Rejection of Claims 13 and 18 Under 35 U.S.C. § 103(a) as Being Unpatentable over Laske et al. in view of Alferness et al.

Claims 13 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Laske et al. in view of Alferness et al. Appellant respectfully traverses this rejection. Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. *See* 37 C.F.R. § 1.75(c).

Appellant submits that the rejection has not established a case of obviousness since the rejection has not shown that each element is taught by the cited patents. Appellant incorporates the above-discussion with respect to the independent claims, and how Laske et al. fails to establish all of the elements. Appellant submits that Alferness et al. does not supply the missing elements.

Additionally, for reasons analogous to those stated above, the Final Office Action fails to provide a legally sufficient motivation to combine the references, and, when considered as a whole, Laske et al. teaches away from making the selective modification as suggested in the Final Office Action. Accordingly, reconsideration and allowance of claims 13 and 18 are respectfully requested.

8. SUMMARY

For the reasons argued above, claims 1-20 were not properly rejected under either § 102(b) or § 103(a). It is respectfully submitted that the claims are patentable over the cited art. Therefore, Appellant respectfully requests reversal of all bases of rejection of all claims.

Respectfully submitted,

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By their Representatives,

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Date January 15, 2007 By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 15 day of January 2007.

Name

Signature

CLAIMS APPENDIX

1. A lead assembly comprising:

a lead body extending from a lead proximal end to a lead distal end and having an intermediate portion therebetween, the lead body including a tine interface section;

at least one tine coupled with the lead body at a tine coupling portion, each at least one tine having a top surface and a bottom surface, the at least one tine having a first position extended away from the lead body, the at least one tine having a second collapsed position;

at least one first recessed portion formed on the lead body at a first longitudinal location along the tine interface section of the lead body;

at least one second recessed portion formed on the lead body at a second longitudinal location along the tine interface section of the lead body;

the at least one first recessed portion longitudinally disposed between the tine coupling portion and the at least one second recessed portion; and

wherein the at least one first recessed portion is recessed away from the bottom surface of the at least one tine when the at least one tine is disposed in the second collapsed position.

2. The lead assembly as recited in claim 1, wherein the at least one first recessed portion extends only a portion around a perimeter of the lead body.

3. The lead assembly as recited in claim 1, wherein the lead body has a first cross-sectional area at the at least one first recessed portion, and the lead body has a second cross-sectional area at the at least one second recessed portion, and the first cross-sectional area is smaller than the second cross-sectional area.

4. The lead assembly as recited in claim 1, wherein the lead body has a first cross-sectional area at the tine interface section, and the lead body has a second cross-sectional area at a second area between the at least one tine and the lead distal end, and the first cross-sectional area is less than 10% smaller than the second cross-sectional area.

5. The lead assembly as recited in claim 1, wherein the lead body has a first transverse dimension and a second transverse dimension each at a longitudinal location along the first recessed portion, and the first transverse dimension is greater than the second transverse dimension.

6. The lead assembly as recited in claim 1, wherein the at least one tine is defined in part by a tine length, and the at least one first recessed portion has a second longitudinal length, and the second longitudinal length is less than the tine length.

7. The lead assembly as recited in claim 1, wherein the intermediate portion of the lead body has a first cross-section, the first recessed portion has a second cross-section, and the second recessed portion has a third cross-section, and the first cross-section, the second cross-section, and the third cross-section are each different from one another.

8. A lead assembly comprising:

a lead body extending from a lead proximal end to a lead distal end and having an intermediate portion therebetween, the lead body having a tine interface section;

at least one tine coupled with the lead body at a tine coupling portion, each at least one tine having a top surface and a bottom surface, the at least one tine having a first position extended away from the lead body, the at least one tine having a second collapsed position;

at least one first portion formed on the lead body at a first location along the tine interface section of the lead body, the at least one first portion having a first cross-sectional shape;

at least one second portion formed on the lead body at a second location along the tine interface section of the lead body, the at least one second portion having a second cross-sectional shape;

the first cross-sectional shape is different than the second cross-sectional shape; and

the at least one first portion longitudinally disposed between the tine coupling portion and the at least one second portion.

9. The lead assembly as recited in claim 8, wherein the first cross-sectional shape has a substantially smaller cross-sectional area than the second cross-sectional shape.

10. The lead assembly as recited in claim 8, wherein the first cross-sectional shape includes one or more recessed portions.

11. The lead assembly as recited in claim 10, wherein the one or more recessed portions extend only a portion around a perimeter of the lead body.

12. The lead assembly as recited in claim 8, wherein the second cross-sectional shape includes one or more recessed portions.

13. The lead assembly as recited in claim 10, wherein the one or more recessed portions extend only a portion around a perimeter of the lead body.

14. The lead assembly as recited in claim 8, wherein the at least one first portion is recessed away from the bottom surface when the at least one tine is disposed in the collapsed position.

15. A method comprising:

disposing a conductor within a lead body, the lead body including a tine interface portion;

coupling one or more tines with the lead body, the one or more tines collapsible from a first extended position to a second collapsed position, the one or more tines having a top surface and a bottom surface;

forming a first recessed portion along the lead body at a first longitudinal location along the tine interface portion, wherein forming the first recessed portion includes recessing the first recessed portion away from the bottom surface when the one or more tines are disposed in the second collapsed position; and

forming a second recessed portion along the lead body at a second longitudinal location along the tine interface portion.

16. The method as recited in claim 15, further comprising collapsing the one or more tines to the second collapsed position at a tine interface portion.

17. The method as recited in claim 16, wherein forming the first recessed portion includes forming a non-circular cross-section at the tine interface portion.

18. The method as recited in claim 17, wherein forming the second recessed portion includes forming a second non-circular cross-section at the tine interface portion.

19. The method as recited in claim 15, wherein forming the first recessed portion includes forming the first recessed portion with a smaller cross-sectional area than the second recessed portion.

20. The method as recited in claim 15, wherein forming the first and second recessed portions includes forming the first recessed portion with at least one of a different cross-section than the second recessed portion or a different cross-sectional shape than the second recessed portion.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.